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Re: Joint Bayer CropScience and Valent U.S.A. Corporation Response to Clothianidin Petition Comments to Docket # EPA-HQ-OPP-2012-0334 (submitted electronically)

Bayer CropScience LP ("Bayer") and Valent U.S.A. Corporation ("Valent") respectfully submit comments regarding the "Emergency Citizen Petition" (EPA-HQ-OPP-2012-0334-0002) ("Petition"), dated March 20, 2012, requesting the immediate suspension of the registration of clothianidin insecticides based on alleged imminent harm of pollinators, as well as initiation of special review and cancellation proceedings, and issuance of a stop sale, use, and removal order ("SSURO"). These comments build on the previously submitted comments ("Preliminary Comments") (Regulations.gov; EPA-HQ-OPP-2012-0334-0008) focused on the imminent harm allegations in the petition and the Petitioners' request for suspension and an SSURO. We support the July 17 decision of the U.S. Environmental Protection Agency ("EPA" or "Agency") to deny the Petitioners' request to suspend clothianidin's registration based on allegations of imminent harm (Regulations.gov.; EPA-HQ-OPP-2012-0334-0006), and provide the following additional information and attached documents in response to the Agency's invitation for public comment on its decision and on the remainder of the Petition's claims.

In general our comments herein address 1) technical issues raised in the Petition and relating to the EPA Office Pesticide Programs Environmental Fate and Effects Division's (EFED) technical support document; and 2) additional legal and regulatory comments not addressed in Bayer's and Valent's Preliminary Comments (Regulations.gov; EPA-HQ-OPP-2012-0334-0008). Following is an introduction to and executive summary of points made in the attached documents.

- Clothianidin-containing products, when used according to label directions, present a high degree of benefit in agricultural production.
- Clothianidin's flexibility of use as a seed dressing, as well as soil and foliar application, are outstanding attributes in its usefulness within integrated pest management programs. Comments previously submitted to this docket as well as to the Registration Review docket for clothianidin (Regulations.gov; EPA-HQ-OPP-2011-0865) highlight the important role this chemical plays in controlling key agricultural pests while reducing the chemical burden in the environment vs. older, broader-spectrum chemicals. The comments cite low environmental impact and favorable worker safety profile, in addition to economic value from targeted pest control, among the benefits that farmers and university specialists recognize with clothianidin.
- Acute bee-related incidents in the U.S. alleged to be related to clothianidin exposure are remarkably few compared to the magnitude of use in terms of acres and number of crops, whether treated by soil, foliar or seed dressing.
- Laboratory research has shown clothianidin to be acutely toxic to bees, as are many other insecticides and other pesticides. Neonicotinoids, however, have had amongst the least frequently detected residue levels in bee hives in large scale monitoring studies. Guttation water is not found to be a significant route of exposure.
- The symptoms of Colony Collapse Disorder (CCD) are inconsistent with effects observed following bee exposure to clothianidin, whether in commercial practice or research studies. As explained in Bayer's and Valent's Preliminary Comments, scientific data do not support any relationship between these limited acute exposure incidents resulting in the death of individual bees, and the allegations relating to colony- and population-level declines in bee populations that form the basis of the Petition.
- Contrary to the claims of the Petition, bee decline in Europe has not been linked to the use of pesticides in general or neonicotinoids in particular. Despite widespread use of clothianidin and other neonicotinoid insecticides in Europe, a recent report from the OPERA Research Centre in Europe finds that CCD as described in the USA has not been observed there.
- To date, various independent research conducted throughout the world has concluded that the stressors causing chronic decline of honeybee populations are multifactorial in nature. Factors that have been implicated as potential contributors include disease/parasites, especially *Varroa* mites and *Nosema* fungus, nutrition, bee management practices, habitat fragmentation, and agricultural practices.
- Contrary to the Petition's allegation, there is no evidence that toxicity of clothianidin or other nitroguanidine products to bees is synergistically enhanced by fungicides or other chemicals under lab or field conditions. Also, when all of the available data on the interaction of

neonicotinoids and the hive parasite *Nosema* are considered, no correlation between neonicotinoid exposure in the field and infection by *Nosema* is supported.

- Allegations that sub-lethal exposures to neonicotinoids are leading to bee population declines are not consistent with large scale observations, field studies or studies conducted at levels representative of field exposures. Scientists who have reviewed and weighed all relevant information continue to conclude that, while lethal and sublethal effects of neonicotinoid insecticides on individual bees have been produced in laboratory studies with unrealistic exposures, no adverse effects at colony level have been observed in field studies with field-realistic exposures.
- One of the desirable attributes of clothianidin is that it is sufficiently persistent to protect seeds and seedlings from pest insects until crop plants are well established. Studies on the nitroguanidine chemical class indicate there is no scientific evidence that the low levels of these insecticides increase significantly in nectar and pollen of agricultural crops with repeated use.
- The Petition provides no legally sufficient basis for the initiation of cancellation or special review proceedings, and should be denied in total. The Petition is facially deficient because it fails to adequately address whether the harms allegedly elicited under artificial exposure conditions are likely to occur in the environment from actual clothianidin use, and fails to address whether the alleged harm is outweighed by the extensive environmental and agricultural benefits of clothianidin. Substantial scientific data available overwhelmingly confirm that clothianidin use poses no unreasonable risk to human health or the environment.
- The Petitioners's claims that the registrants of clothianidin failed to take appropriate action to fulfill conditions of registration are factually and legally meritless. The required pollinator field study was completed and submitted to EPA in 2006. The fact that EPA may require additional data at a given point in time does not mean that the existing data is insufficient to support a risk/benefit determination.
- The Petitioners provide no basis on which EPA should consider cancellation or Special Review proceedings based on endangered species concerns. EPA is already implementing the relief requested in the Petition as part of the statutory Registration Review process. Moreover, the endangered species allegations in the Petition fall far short of alleging a risk to the continued existence of an endangered or threatened species, the standard for initiating special review or cancellation proceedings based on endangered species concerns.
- A number of the Petitioners recently submitted a notice of intent to file a lawsuit raising the same ESA claims made in the Petition, before EPA has even had the chance to issue a final decision on the Petition, and similar ESA claims are already being litigated in federal court. In addition, petitioners raised many of their other arguments in a letter request denied by EPA in 2011, a result the petitioners elected not to appeal. The petitioners' pattern of filing

successive and repetitious claims provides an independent ground for denial of the current Petition.

- We recognize and appreciate EPA's obligation to consider the opinions of many stakeholders with varying points of view on the matter of clothianidin's risks and benefits. We believe that a common goal of responsible and safe use of pesticides may be achieved through an honest and open debate incorporating *all* available science and perspectives. To this end, we support the process laid out thus far by EPA, including 1) expedited Registration Review, 2) consideration of all relevant, available data in establishing a science-based pollinator risk assessment scheme, and 3) use of the Pesticide Program Dialogue Committee to define risk management options balancing environmental protection with the needs of agricultural production.

As providers of plant protection products to farmers and consumers who depend on them, and as citizens with concerns for our families and the natural environment, we share a strong interest in the health and safety of pollinators and other creatures, while contributing to a healthful and affordable supply of food and fiber. Thus, Bayer and Valent are actively engaged with EPA and other stakeholders, and are prepared not only to continue fulfilling our regulatory responsibilities, but to add to the body of knowledge supporting label language and best management practices that will ensure continued safe and sustainable use of our products in agriculture and other applications. To this end we fully support EPA's approach to protect pollinator health, solidly rooted in science, and recognizing the significant environmental and economic benefits of our products.

Respectfully submitted,

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Attachments

1. Joint Bayer CropScience and Valent U.S.A. Corporation Response To Clothianidin Petition - Technical Response
2. Joint Bayer CropScience and Valent U.S.A. Corporation Response To Clothianidin Petition - Legal and Regulatory Comments